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EXAMINER

LLOYD, EMILY M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,261	<b>Applicant(s)</b> COHEN ET AL.	
	<b>Examiner</b> EMILY M. LLOYD	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14-25, 27 and 78-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-25, 27, and 78-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This office action is in response to the amendment filed 4 April 2008. The Examiner acknowledges the amendment to claim 14 and the addition of claims 88 and 89. Currently, claims 1-12, 14-25, 27, and 78-89 are pending.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7, 9-12, 14-20, 22-25, 27, 78-80, 83-85, and 89 rejected under 35 U.S.C. 103(a) as being unpatentable over International Publication Number WO 01/30242 (Paternuosto).

Regarding claim 1, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through the open top (5th paragraph of page 4), and a portion of the elongate container adjacent the open bottom defining a restriction to prevent the plurality of tissue samples from passing through the restriction and exiting the container via the open bottom (page 4 paragraph 6, where the restriction is opening 24 Figure 7).

Paternuosto does not disclose that the restriction is an hour-glass shape that defines a restriction smaller than the open bottom. Instead, Paternuosto indicates that the open bottom itself is a restriction for keeping biopsy samples in the device.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an hour-glass shape that

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defines a restriction smaller than the open bottom because Applicant has not disclosed that the hour glass shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Paternuosto's opening at the bottom of the container, and applicant's invention, to perform equally well with either the opening taught by Paternuosto or the claimed hour-glass shape because both types of openings would perform the same function of preventing an biopsy sample from falling-out equally well considering the typical size of an biopsy sample.

Therefore, it would have been prima facie obvious to modify Paternuosto to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Paternuosto.

Regarding claim 14, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through the open top (5th paragraph of page 4), and a bottom portion of the elongate container closer to the open bottom

than to the open top is configured to prevent tissue samples from exiting the container via the open bottom (page 4 paragraph 6, where the restriction is opening 24 Figure 7).

Paternuosto does not disclose that the restriction is an hour-glass shape that defines a restriction smaller than the open bottom. Instead, Paternuosto indicates that the open bottom itself is a restriction for keeping biopsy samples in the device.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an hour-glass shape that defines a restriction smaller than the open bottom because Applicant has not disclosed that the hour glass shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Paternuosto's opening at the bottom of the container, and applicant's invention, to perform equally well with either the opening taught by Paternuosto or the claimed hour-glass shape because both types of openings would perform the same function of preventing an biopsy sample from falling-out equally well considering the typical size of an biopsy sample.

Therefore, it would have been prima facie obvious to modify Paternuosto to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Paternuosto.

Regarding claims 2 and 15, Paternuosto teaches the devices of claims 1 and 14, wherein the cutting portion (front rim 12 Figures 5 and 7) selectively couples to the open top of the elongate container (Figure 7) and defines a through hole (hole 18 Figures 5

and 7) in flow communication with the open top, the cavity, and the open bottom (Figure 7).

Regarding claims 3 and 16, Paternuosto teaches the devices of claims 1 and 14, wherein the cutting portion comprises an upper jaw (half-shell 10A Figure 6) and a lower jaw (half-shell 10B Figure 7) configured to cut tissue when the upper jaw mates with the lower jaw (last paragraph of page 5 and Figures 2 and 3).

Regarding claims 4 and 17, Paternuosto teaches the devices of claims 3 and 16, wherein the lower jaw (half-shell 10B Figure 7) includes a through hole (hole 18 Figure 7) in flow communication with the open top and the open bottom, and wherein the lower jaw is coupled to the open top of the elongate container such that the through hole is in flow communication with the open top, the cavity, and the open bottom (adhesive 30 Figure 7 and the 4th paragraph of page 5).

Regarding claims 5 and 18, Paternuosto teaches the devices of claims 3 and 16, wherein the upper jaw includes a protrusion (central portion 26 Figure 6) configured to push the plurality of tissue samples into the cavity (last paragraph of page 5).

Regarding claims 6 and 19, Paternuosto teaches the devices of claims 5 and 18, wherein the protrusion extends around an edge of the upper jaw (central portion 26 is around the inner edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claims 7 and 20, Paternuosto teaches the devices of claims 3 and 16, wherein the upper jaw is configured to restrict the plurality of tissue samples from adhering to the upper jaw (central portion 26 Figure 6 and last paragraph of page 5).

Regarding claims 9 and 22, Paternuosto teaches the devices of claims 3 and 16, wherein at least one of the upper jaw and the lower jaw has a support portion (support portion 16 Figure 2 and 3, see also the last paragraph of page 5) configured to allow the upper jaw and the lower jaw to rotate with respect to each other (last paragraph of page 3).

Regarding claims 10 and 23, Paternuosto teaches the devices of claims 1 and 14, wherein the elongate container includes an angled base wall adjacent the open top (the wall of container element 22 adjacent base wall 14 is angled and adjacent the open top).

Regarding claims 11 and 24, Paternuosto teaches the devices of claims 1 and 14, wherein the elongate container is configured to restrict the plurality of tissue samples from adhering to an inner wall of the elongated container (openings 24 Figure 7).

Regarding claims 12 and 25, Paternuosto teaches the devices of claims 1 and 14, wherein the elongated container includes at least one hole in a side wall of the elongate container (openings 24 on the sides of container element 22, Figure 7).

Regarding claim 27, Paternuosto teaches the device of claim 14, wherein the portion of the elongate container adjacent the open bottom has a restriction that is smaller than the open bottom (see rejection of claim 14 above).

Regarding claims 78 and 83, Paternuosto teaches the devices of claims 1 and 14, wherein the portion of the elongate container adjacent to the open bottom is configured to mate with a flushing device (opening 24 Figure 7).



Regarding claims 79 and 84, Paternuosto teaches the devices of claim 6 and 19, wherein the protrusion is adjacent to the outer edge of the upper jaw (central portion 26 is adjacent to the outer edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claims 80 and 85, Paternuosto teaches the devices of claims 79 and 84, wherein the protrusion is oval shaped (central portion 26 would be circular based on Figures 4 and 6; a circle is a particular case of an ellipse (a type of oval) where the major axis is equal in length to the minor axis).

Regarding claim 89, Paternuosto teaches the device of claim 1, wherein the portion of the elongate container adjacent the open bottom is closer to the open bottom than the open top (see rejection of claim 1 above).

6. Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto as applied to claims 1-7, 9-12, 14-20, 22-25, 27, 78-80, 83-85, and 89 above, and further in view of United States Patent 5662671 (Barbut et al.).

Regarding claims 8 and 21, Paternuosto teaches the devices of claims 3 and 16 in the 103(a) rejections above. Paternuosto does not teach that the upper jaw defines a plurality of holes. Barbut et al. teaches the use of the upper jaw defining a plurality of holes (perforations 282 and 285 in clam shells 280 and 283, Figure 15A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such an upper jaw defining a plurality of holes as taught by Barbut et al. to provide for the movement of fluid and air while retaining the biopsy sample in the device in the invention of Paternuosto because this would provide an additional means of discharging air and liquids, which would better help the biopsy samples to move into the

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container element (Paternuosto 6th paragraph page 4) and permit blood flow out of the device (Barbut et al. Column 17 lines 45-48).

7. Claims 81-82 and 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto as applied to claims 1-7, 9-12, 14-20, 22-25, 27, 78-80, 83-85, and 89 above, and further in view of United States Patent 2778357 (Leibinger et al.).

Regarding claims 81 and 86, Paternuosto teaches the devices of claims 79 and 84 in the 103(a) rejections above. Paternuosto does not disclose that the protrusion surrounds an inner non-protruding portion. Leibinger et al. teaches the use of a protrusion surrounding an inner non-protruding portion (jaw member 13b Figure 2 of “male shape” Column 2 lines 21-22 that “penetrates ... into the jaw member 13a” Column 2 lines 20-21; “open construction” Column 2 line 24 indicates a non-protruding portion 13c Figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a protrusion surrounding an inner non-protruding portion as taught by Leibinger et al. to provide for the movement of fluid and air while retaining the biopsy sample in the device in the invention of Paternuosto because this would provide an additional means of discharging air and liquids, which would better help the biopsy samples to move into the container element (Paternuosto 6th paragraph page 4).

Regarding claims 82 and 87, Paternuosto as modified by Leibinger et al. teach the devices of claims 81 and 86, wherein the inner non-protruding portion defines at

least one ventilating hole (Leibinger et al. "open construction" Column 2 line 24, 13c Figure 2).

8. Claim 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto as applied to claims 1-7, 9-12, 14-20, 22-25, 27, 78-80, 83-85, and 89 above, and further in view of United States Patent 4763669 (Jaeger).

Regarding claim 88, Paternuosto teaches the device of claim 14 in the 103(a) rejection above. Paternuosto does not disclose that the cutting portion includes a circumferential groove configured to receive a protrusion on the top. Jaeger teaches a cutting portion (cutting section 112 Figures 11 and 12) that includes a circumferential groove configured to receive a protrusion (cutting section 110 meeting cutting section 112, Figure 12, and Column 8 lines 44-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a cutting portion that includes a circumferential groove configured to receive a protrusion as taught by Jaeger in the invention of Paternuosto to "inhibit lateral displacement" (Jaeger Column 8 lines 48-49) and for use in "cutting very sturdy tissues" (Jaeger Column 8 lines 50-51).

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1-12, 14-25, 27, and 78-89 have been considered but are moot in view of the new ground(s) of rejection. A new ground(s) of rejection is made in view of a different interpretation of the previously applied reference.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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